

Dkt No. PP01468.103

Serial No. 09/187,661

## **REMARKS**

### **Introductory Comments**

Claims 1, 3, 4, 13, 16-20 and 28-44 were examined in the Office Action under reply and rejected under (1) 35 U.S.C. §112, second paragraph; and (2) the judicially created doctrine of obviousness-type double patenting. The rejections are respectfully traversed for reasons discussed below.

### **Overview of the Above Amendments**

Claims 5-7, 9-11, 14, 15 and 21-27 have been canceled herein as drawn to a nonelected invention. Claims 1, 16, 34 and 42 have been amended to recite the invention with greater particularity. Specifically, claims 1 and 34 now recite that the IGF-I is present in a concentration of "about 250 mg/ml or greater." Additionally, claims 1, 34 and 42 recite that the pH is "pH 5.0 or greater." Support for these recitations can be found in the claims as originally filed, as well as in the specification at, e.g., page 5, lines 8-10; page 6, line 6; and page 20, lines 29-30. Claim 16 has been amended to delete the alternative recitation and new claims 45-47 have been added that correspond to the alternative expression deleted from claim 16.

Amendment of these claims is made without intent to abandon any originally claimed subject matter and without intent to acquiesce in any rejection of record.

### **The Obviousness-type Double Patenting Rejections**

Claims 1, 3, 4, 13, 16-20 and 28-44 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 2-9, 12-16 and 26-51 of copending Application Serial No. 09/187,780. Applicants are submitting a Terminal Disclaimer, disclaiming the terminal part of any patent granted on the present application that would extend beyond the expiration date of any patent granted on the '780 application. Thus, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

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Claims 1, 3, 4, 13, 16-20 and 28-44 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-40, 44-48, 85-93, 97-107, 111 and 112 of copending Application Serial No. 09/188,051. Applicants traverse this rejection.

The compositions claimed in the present application and those claimed in the '051 application are quite distinct. In particular, the present claims pertain to low salt-containing, highly concentrated compositions with the amount of IGF-I present being about 250 mg/ml or greater. As explained in the application, these compositions contain IGF-I in the form of a highly concentrated syrup. One way to prepare the subject compositions is by using a compound containing a guanidinium group in order to enhance the solubility of IGF-I. However, if used, the solubility enhancer is removed in order to obtain the highly concentrated syrup form of the present invention (see, the Examples).

The compositions of the '051 application, on the other hand, include a solubilizing compound and the claims have now been amended to read that the IGF-I is present at a concentration of about 12 mg/ml to about 200 mg/ml. Thus, not only is the concentration of IGF-I in the compositions different, the IGF-I is in a different physical form.

The claims in the '051 application do not suggest the attributes of the compositions claimed herein. Thus, withdrawal of the obviousness-type double patenting rejection over the '051 application is respectfully requested.

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35 U.S.C. §112, second paragraph

The Examiner rejected claims 1, 3, 4, 13, 16-20 and 28-44 under 35 U.S.C. §112, second paragraph, as indefinite. The Examiner objected to the phrases "at least about 250 mg/ml" and "greater than about pH 5.0." The Examiner argues "it is unclear whether the concentration is greater than 250 mg/ml as to 'at least', or less than 250 mg/ml as to 'about'; and whether the pH is higher than 5.5 as to 'greater than', or less than 5.5 as to 'about'". Office Action, page 5. However, applicants submit that the present claims are indeed clear.

As explained above, claims 1 and 34 have been amended as proposed by the Examiner and now recite that the IGF-I is present in a concentration of "about 250 mg/ml or greater." Additionally, claims 1, 34 and 42 now recite that the pH is "pH 5.0 or greater." Accordingly, the rejections under 35 U.S.C. §112, second paragraph have been overcome and withdrawal thereof is respectfully requested.

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### CONCLUSION

Applicants respectfully submit that the claims are novel and nonobvious over the art and comply with the requirements of 35 U.S.C. §112. Accordingly, allowance is believed to be in order and an early notification to that effect would be appreciated.

Please direct all further communications in this application to:

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Respectfully submitted,

Dated: \_\_\_\_\_

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By: \_\_\_\_\_

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